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510(K) SUMMARY
(as required by 807.92(c))

JUN 18 2010

Regulatory Correspondent	Arthur Ward Regulatory and Marketing Services 962 Allegro Ln Apollo Beach, FL 33572 (813) 645-2855 award@ajwtech.com / Awconsltng@aol.com
Submitter of 510(k):	APP Pharmaceuticals, LLC 1501 East Woodfield Rd, Suite 300 East Schaumburg, IL 60173 USA Phone: (847) 330-3898 Fax: (847) 413-8570
Contact Person:	Aditi Dron
Date of Summary:	June 18, 2010
Trade/Proprietary Name:	Heparin Lock Flush Solution USP
Classification Name:	Heparin, vascular access flush
Product Code:	NZW
Intended Use:	Heparin Lock Flush Solution, USP product code 505701 (10 USP units/mL) and product code 504901 (100 USP Units/mL), is intended to maintain patency of an indwelling venipuncture device designed for intermittent injection or infusion therapy or blood sampling.
Device Description:	The Heparin Lock Flush Solution, USP product code 505701 comes in concentration of 10 USP Units/mL, and in strengths of 10 USP units. The Heparin Lock Flush Solution, USP product code 504901 comes in concentration of 100 USP Units/mL, and in strength of 100 USP units. These two product codes are packaged in 3 cc plastic vials

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Technological Characteristics:

Heparin Lock Flush Solution, USP, product codes 505701 (10 USP Units/mL, preservative-free, 1 mL fill volume) and 504901 (100 USP Units/mL, preservative-free, 1 mL fill volume) are single dose preservative free presentations of Heparin Lock Flush Solution, USP. They differ from the other FDA-approved product codes (504401, 504411, 504501, and 504505) since these are preserved with methylparaben and propylparaben. Another existing product code (1710) is also preservative free but it has a larger fill volume of 10 mL per vial.

Predicate Device:

K001795 - 10 & 100 USP Units/mL Heparin Vascular Access Flush Device

Substantial Equivelance:

APP claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K001795. APP claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principles and physical operational specifications as compared to the predicate devices. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 9 of this submission. These differences have no effect on safety and effectiveness.

Test Summary:

APP has performed cytotoxicity and hemolysis tests to demonstrate the biocompatibility of the final finished sterilized Heparin Lock Flush Solutions, USP. A MEM Elution test to determine the cytotoxicity of extractable substances was performed. The test results demonstrate that the sample met USP and ISO requirements. Therefore, the sample was found to be non-cytotoxic. The hemolysis test was conducted in accordance with US FDA regulations per 21 CFR Part 58 utilizing the ASTM Hemolysis (Direct Contact) Method.

The samples of Heparin Lock Flush Solution, USP were found to be non-hemolytic. APP has also developed a test method to detect the presence of a potential leachable from the polypropylene vials into the Heparin Lock Flush Solution, USP. The potential leachable is 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene (TMTBB). This compound has been identified by the resin manufacturer as a compound present in their resin material used to produce the vial used for the Heparin Lock Flush Solution, USP. APP analyzed freshly prepared samples as well as stability samples of Heparin Lock Flush Solution, USP using a high performance liquid chromatography (HPLC) limit test method for the determination of TMTBB. The results demonstrated that TMTBB is not detected in Heparin Lock Flush Solution, USP following sterilization or over the shelf life of the solution.

Test Conclusion:

The biocompatibility of Heparin Lock Flush Solution, USP following sterilization has been tested using cytotoxicity and hemolysis testing. Furthermore, potential leachables from the polypropylene vials into the Heparin Lock Flush Solution, USP have also been studied. The results of these studies indicate that APP's Heparin Lock Flush Solution, USP product codes 504901 and 505701 are non-cytotoxic, non-hemolytic, and free from leachables. Therefore, we consider the devices to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APP Pharmaceuticals, LLC
C/O Mr. Arthur Ward
Regulatory and Marketing Services
962 Allegro Lane
Apollo Beach, Florida 33572

JUN 18 2010

Re: K092938
Trade/Device Name: Heparin Lock Flush Solution USP, Models 504901 and 505701
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NZW
Dated: May 19, 2010
Received: May 20, 2010

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092938___

Device Name: Heparin Lock Flush Solution

Indications for Use:

Heparin Lock Flush Solution, USP product code 505701 (10 Units/mL) and product code 504901 (100 USP Units/mL) is intended to maintain patency of an indwelling venipuncture device designed for intermittent injection or infusion therapy or blood sampling.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

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